

The Claims:

The following listing reflects amendments to the claims and replaces all prior versions and listings of claims in this application.

1-25. (Cancelled)

26. (Previously Presented) A method for preparing a dry powder insulin composition, said method comprising:

dissolving insulin in an aqueous buffer at a concentration in the range from 0.01% to 1% to form a solution; and

spray drying the solution to produce particles having an average size below 10 μm .

27. (Currently amended) A method as in claim 26, wherein the insulin is dissolved in a aqueous buffer together with a pharmaceutical carrier, wherein a dry powder having insulin present in individual particles at from 5% to 99% by weight is produced upon spray drying.

28. (Previously presented) A method as in claim 27, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.

29. (Previously presented) A method as in claim 28, wherein the pharmaceutical carrier is a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, maltodextrin and trehalose.

30. (Currently amended) A method as in claim 26 27, wherein the pharmaceutical carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.

31. (Previously presented) An insulin composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include insulin present at from 20% to 80% by weight in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm .

32. (Previously presented) An insulin composition as in claim 31, wherein the composition is substantially free from penetration enhancers.

33. (Previously presented) An insulin composition as in claim 31, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, maltodextrin, and trehalose.

34. (Previously presented) An insulin composition as in claim 31, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.

35. (Previously presented) A method for preparing a dry powder insulin composition, said method comprising:

providing an aqueous solution of insulin and a pharmaceutical carrier dissolved in an aqueous buffer, wherein the insulin is present at 0.01% to 1% by weight and comprises from 20% to 80% of the total weight of insulin and pharmaceutical carrier in the solution; and

spray drying the solution to produce particles comprising both the insulin and the pharmaceutical carrier having an average size below 10 μm and a moisture content below 10%.

36. (Previously presented) A method as in claim 35, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.

37. (Previously presented) A method as in claim 36, wherein the carbohydrate carrier is selected from the group consisting of mannitol, raffinose, lactose, maltodextrin and trehalose.

38. (Previously presented) A method as in claim 35, wherein the carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.

39. (Previously presented) An insulin composition for pulmonary delivery, said composition comprising:

a dry powder of individual particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight, have an average particle size below 10 μm , and have a moisture content below 10%.

40. (Previously presented) An insulin composition as in claim 39, wherein the particles consist essentially of the insulin and the pharmaceutical carrier.

41. (Previously presented) An insulin composition as in claim 39, wherein the composition is substantially free from penetration enhancers.

42. (Previously presented) An insulin composition as in claim 39, wherein the pharmaceutical carrier comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, maltodextrin, and trehalose.

43. (Previously presented) An insulin composition as in claim 39, wherein the pharmaceutical carrier comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.

44. (Previously presented) A method as in claim 26, wherein the composition is substantially free from penetration enhancers.

45. (Previously presented) A method as in claim 26, wherein the particles are substantially amorphous.

46. (Previously presented) A composition as in claim 31, wherein the composition is substantially amorphous.

47. (Previously presented) A method as in claim 35, wherein the particles have a moisture content less than about 5% by weight.

48. (Previously presented) A method as in claim 35, wherein the particles are substantially amorphous.

49. (Previously presented) An insulin composition as in claim 39, wherein the particles have a moisture content less than about 5% by weight.

50. (Previously presented) An insulin composition as in claim 39, wherein the particles are substantially amorphous.

51. (Previously presented) An insulin composition for pulmonary delivery, said composition comprising a dry powder of individual particles including insulin present at from 5% to 80% by weight in a pharmaceutical carrier material, wherein the particles have an average size below 10 μm .

52. (Previously presented) An insulin composition as in claim 51, wherein the composition is substantially free from penetration enhancers.

53. (Previously presented) An insulin composition as in claim 51, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, maltodextrin, and trehalose.

54. (Previously presented) A composition as in claim 51, wherein the composition is substantially amorphous.

55. (Previously presented) A composition as in claim 51, wherein the particles have a moisture content less than about 10% by weight.

56. (Previously presented) A composition as in claim 51, wherein the particles have a moisture content less than about 5% by weight.

57. (Previously presented) A method for preparing a dry powder insulin composition, said method comprising:

providing an aqueous solution of insulin and a pharmaceutical carrier dissolved in an aqueous buffer, wherein the insulin is present at 0.01% to 1% by weight and comprises from 5% to 80% of the total weight of insulin and pharmaceutical carrier in the solution; and

spray drying the solution to produce particles comprising both the insulin and the pharmaceutical carrier having an average size below 10 μm and a moisture content below 10%.

58. (Previously presented) A method as in claim 57, wherein the particles have a moisture content less than about 5% by weight.

59. (Previously presented) A method as in claim 57, wherein the particles are substantially amorphous.